

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effects of vitamin D on insulin resistance in type two diabetic patients

Protocol summary

Summary

217 patients (137 female, 80 male) having diabetes type 2 and age between 20 and 60 years old referred to diabetes Arak clinic were recruited. Inclusion criteria: Absence of hepatic, renal, bone disease, Not receiving anticonvulsant drugs, calcium, anticancer drugs and vitamin D. All of them were examined and information on their age, weight, PTH level, vit D level, BMI, renal and hepatic function tests, lipid profile, FBS, insulin, Ca, P, ALP, albumin, job, income, nutrition, and HOMA-IR were collected. Those with vit deficiency were categorised into three groups: mild deficiency: 20-25 ng/ml of 25-hydroxy vitamin D; moderate deficiency: 10-20 ng/ml of 25-hydroxy vitamin D; sever deficiency: 5-10 ng/ml of 25-hydroxy vitamin D. Patients were then given vit D 50000 units daily for 4 weeks. Their FBS and HoMA-IR were measured and compared before and after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811073216N1**

Registration date: **2010-08-25, 1389/06/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-08-25, 1389/06/03

Registrant information

Name

Afsaneh Talaiei

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1222 5229

Email address

talaiei.a@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2008-12-31, 1387/10/11

Expected recruitment end date

2009-12-31, 1388/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D on insulin resistance in type two diabetic patients

Public title

Effects of vitamin D on insulin resistance in type two diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Absence of hepatic, renal, bone disease, Not receiving anticonvulsant drugs, calcium, anticancer drugs and vitamin D

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **217**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak university

Street address

Arak medical university

City

Arak

Postal code**Approval date**

empty

Ethics committee reference number

5157

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E10, E11.,

ICD-10 code description

Diabetes

Primary outcomes**1****Description**

Insulin resistance

Timepoint

Immediately before intervention and 1 Month after intervention

Method of measurement

HOMA-IR with Blood glucose and Insulin

Secondary outcomes**1****Description**

Fasting Blood Sugar

Timepoint

1 month

Method of measurement

Laboratory methods

Intervention groups**1****Description**

vit D tab 50000 unit oral one month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arak clinic diabetes

Full name of responsible person**Street address****City**

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak university

Full name of responsible person

Dr Ashtiani

Street address

Arak

City

Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak university

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak medical university

Full name of responsible person

Dr Talaei

Position

Endocrinologist

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty